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**FILED
CHARLOTTE, NC**

JUN 27 2017

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA** US District Court
Western District of NC

UNITED STATES of AMERICA and
STATE OF NORTH CAROLINA
ex rel. MARK MCGUIRE,

Plaintiff-Relator,

v.

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY, INC.,

Defendant

Civil Action No.: 3:15-cv-147(FDW)

Filed Under Seal Pursuant to
31 U.S.C. § 3730(b)(2)

**RELATOR DEMANDS
TRIAL BY JURY ON ALL
COUNTS**

AMENDED COMPLAINT

INTRODUCTION

1. This action concerns two distinct frauds committed by the Charlotte-Mecklenburg Hospital Authority, Inc., which does business as the Carolinas HealthCare System (“Carolinas”), to defraud Medicare and the Medicaid program of North Carolina. First, Carolinas overbilled Medicare and Medicaid by fraudulently upcoding bills for urine drug tests (“UDT”) in an effort to increase its revenue. Second, Carolinas knowingly and impermissibly retained overpayments made by government health care programs for the illegally upcoded UDT.

2. Both of these frauds were conducted network-wide in all of the laboratory facilities Carolinas owns which perform outpatient urine drug testing.

PARTIES

3. Plaintiff-Relator Mark McGuire (“Relator”) is an individual who resides in Charlotte, North Carolina. He is the Laboratory Director of Operations at the Carolinas Medical Center (“CMC”) in Charlotte, North Carolina. Relator oversees all of the operations of CMC’s

laboratory, which also serves as the laboratory for Levine's Children's Hospital and is the core lab for the Carolinas Laboratory Network Reference lab.

4. Defendant Charlotte-Mecklenburg Hospital Authority ("Carolinas") is a hospital authority organized under the laws of North Carolina with a principal place of business in Charlotte, North Carolina. Charlotte-Mecklenburg Hospital Authority does business under the name Carolinas HealthCare System.

JURISDICTION AND VENUE

5. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA").

6. This District Court has personal jurisdiction over Carolinas pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Carolinas has sufficient minimum contacts with the United States of America.

7. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) as Carolinas regularly transacts business in this judicial district.

8. Relator is not aware of any public disclosure of the information or allegations that make up this Complaint.

THE CAROLINAS HEALTHCARE SYSTEM

9. Carolinas began as a community hospital in 1943. Since that time, Carolinas has grown into one of the nation's largest health care systems, currently boasting more than 60,000 employees and more than 7,460 licensed beds. Carolinas has an annual budget exceeding \$7.7 billion - comparable to many Fortune 500 companies. Both Carolinas' headquarters and its flagship hospital, CMC, are located in Charlotte, Mecklenburg County, North Carolina.

10. Carolinas both owns and manages health care facilities, including numerous hospitals. The entities that Carolinas owns are known as the Primary Enterprise and most of those entities are owned directly by Carolinas. CMC is the flagship hospital for Primary Enterprise and the entire Carolinas system. CMC includes the Levine Children's Hospital and the Behavioral Health Center CMC - Randolph. Other hospitals that are contained within the Primary Enterprises are Mercy Hospital, Inc., Carolinas Medical Center - Pineville, Carolinas Medical Center - University, Carolinas Medical Center-NorthEast, Carolinas Medical Center-Union, and Cleveland County HealthCare System. These hospitals all perform UDT.

11. The Primary Enterprise system also includes the Physicians Services Group, Carolinas Physicians Network, Inc., the James G. Cannon Research Center, Carolinas Medical Center - Lincoln, Carolinas Rehabilitation - Main and Mount Holly, Huntersville Oaks, Sardis Oaks. Although Mercy, Cleveland County, MHRI, Carolinas-Anson and Palliative are separately incorporated, each of them are also part of the Primary Enterprise.

12. Carolinas' corporate officials direct the operation of each of the entities that comprise the Primary Enterprise. Each of the facilities within the Primary Enterprise follow the same reimbursement, billing and compliance policies, and they share the same chargemaster system for billing Medicare and Medicaid. Most of the Primary Enterprise facilities billed Medicare and Medicaid through Carolinas, and Carolinas had the provider agreement with Medicare and Medicaid. On information and belief, Mercy, Cleveland County, MHRI, Carolinas-Anson and Palliative had their own provider agreements with Medicare and Medicaid, but, as described above, followed the same billing and reimbursement policies as Carolinas.

13. Despite being one of the largest health care systems in the United States, Carolinas has had periods of difficulty. Carolinas' operating margin weakened in 2013, and

decreased sharply, reaching negative levels, in the first quarter of 2014. In 2013, Carolinas' management attempted to restore system profitability and operating cash flow. The hope was, by reducing costs and growing revenue, Carolinas could achieve "at least break-even results for full fiscal 2014." It was during Carolinas' tumultuous first quarter of 2014 that Relator informed his superiors about the upcoding scheme and Carolinas' impermissible retention of Medicare and Medicaid dollars.

MEDICARE, MEDICAID AND URINE DRUG TESTING

14. The Health Insurance for the Aged and Disabled Act (Title XVIII of the Social Security Act) known as "Medicare," is a health insurance program designed to assist the nation's elderly meet healthcare costs. In addition, Medicare also provides medical coverage for many individuals who are permanently disabled under the Social Security Act. Medicare includes hospital insurance, Part A, and supplementary medical insurance ("SMI"), Part B. Medicare Part B is a voluntary medical insurance plan designed to supplement hospital insurance coverage. Part B is financed by premiums paid monthly by enrollees and by the federal government. Medicare Part B coverage includes most outpatient UDT.

15. The Medicaid Program is authorized by Title XIX of the Social Security Act and Title 42 of the Code of Federal Regulations. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the indigent and disabled. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a.

16. Urine drug testing for clinical medicine purposes is a major business in the United States. Thousands of drug tests are routinely performed in connection with medical treatment. UDT is done to determine if a patient is taking drugs which might interfere with planned medical treatment; other times UDT is performed in order to ensure that the patient is compliant with his

or her prescription regimen. Such tests are very frequently administered in connection with patients undergoing pain management therapy.

17. When ordered by a physician in the course of treating a patient, UDT may be reimbursed by Medicare, Medicaid and other federally funded health care programs. Both federal and state governments reimburse a large percentage of all clinical UDT conducted in the United States. Persons who are disabled as a result of chronic pain are the types of patients who undergo UDT on a regular basis, and many of these patients' tests are covered by Medicare. A significant percentage of patients with chronic pain management problems are also Medicaid patients.

REGULATORY BACKGROUND

A. Clinical Laboratory Test Complexity

18. One of the principal factors used by Medicare and Medicaid in determining the rate of reimbursement for outpatient UDT is the complexity of the testing. A laboratory test's complexity is determined by the Food and Drug Administration ("FDA"). Laboratory tests are categorized as either (1) waived tests; (2) tests of moderate complexity; or (3) tests of high complexity. See 42 CFR § 493.5. The lowest level of complexity is waived complexity. Tests in this category are simple laboratory tests which are cleared by the FDA for home use and employ methodologies that are so simple and accurate that the likelihood of an erroneous result is negligible. See 42 CFR § 493.15. Examples of waived complexity tests are dipstick or tablet reagent urinalysis (non-automated), and urine pregnancy tests.

19. The FDA uses seven criteria to determine whether a laboratory test falls into the moderate complexity or high complexity categories: (1) knowledge, (2) training and experience, (3) reagents and materials preparation, (4) characteristics of operational steps, (5) calibration, quality control, and proficiency testing materials, (6) test system troubleshooting and equipment maintenance, and (7) interpretation and judgment. The FDA maintains a database that is updated

monthly and lists records of all commercially marketed laboratory tests that have been categorized. Manufacturers of equipment used in certified laboratories keep track of whether their machinery is capable of performing moderately complex or highly complex testing and are always available as a resource in case a provider is uncertain of the complexity level of the tests conducted in its laboratory.

B. CMS Reimbursement for Clinical Laboratory Services

20. Under § 1833(h) of the Social Security Act, outpatient clinical laboratory services are paid based on a fee schedule, known as the Clinical Laboratory Fee Schedule (“CLFS”). CLFS is comprised using the Healthcare Common Procedure Coding System (“HCPCS”) - the required medical billing process used by CMS to ensure that insurance claims are processed in an orderly and consistent manner.

21. HCPCS is divided into two main subsystems, level I and level II. HCPCS level I is made up of the American Medical Association’s Current Procedural Terminology (“CPT”) codes, which are descriptive terms and identifying codes that are used to identify medical services and procedures provided by health care professionals and are used to bill both public and private health insurers. Level II of the HCPCS is a standardized, alphanumeric coding system, used primarily to identify non-physician services. Laboratory services, such as UDT, are coded under HCPCS level II.

22. HCPCS codes related to laboratory testing change each year. CMS identifies new HCPCS codes, including any modifiers or changes to existing codes, by providing an updated listing of these tests to Medicare carriers and fiscal intermediaries on an annual basis. CMS also provides Medicare carriers and fiscal intermediaries with the corresponding billing amount for each HCPCS code.

C. January 2011 CMS Reimbursement Change for UDT

23. From 2000-2010, CMS experienced a dramatic increase in reimbursements for rapid diagnostic tests, including UDT. In an effort to curb potential abuse of over-reimbursement related to these tests, CMS changed the reimbursement rules with respect to two HCPCS codes for UDT. On February 11, 2011, CMS released SE1105 - a publication directed to clinical diagnostic laboratories that addressed the problems of over-reimbursement related to UDT. SE1105 set out changes to the coding schemes and Medicare's reimbursement rules for UDT that would go into effect on January 1, 2011. *See SE1105, attached as Exhibit 1.* These changes applied to all Medicare providers that performed UDT, including Carolinas' facilities. In 2011, North Carolina Medicaid adopted the same billing and reimbursement rules changes relating to UDT.

24. One of the major changes documented in SE1105 involved HCPCS code G0431, the code for qualitative drug screens for multiple drug classes. Previously, this code was used to bill for drug tests of all complexity levels. In 2010, CMS identified G0431 as a code that needed to be refined based on unnecessary and excessive utilization. Effective January 1, 2011, CMS introduced a new code, G0434, which was defined as "Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter." (emphasis added). SE1105 instructed providers to use the new code when reporting "very simple testing methods" or when utilizing "a moderately complex reader device." Additionally, SE1105 instructed providers that:

(t)his code is also used to report any other type of drug screen testing using test(s) that are classified as Clinical Laboratory Improvement Amendments (CLIA) moderate complexity test(s) (emphasis added).

25. SE1105 also redesignated and reclassified G0431. Its new description was “Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter” (emphasis added). CMS explicitly limited its application to complex tests: “*This code may only be reported if the drug screen test(s) is classified as CLIA high complexity test(s)*” (emphasis added).

26. As a result of these reimbursement changes, after January 1, 2011, only drug screens performed on equipment capable of performing high complexity testing could be billed under G0431. SE1105 authorized no exceptions.

27. Prior to 2011, providers like Carolinas could receive multiple reimbursements for multiple drugs tested for on a multi-drug test device, even though the device was only performing a single test. CMS changed that rule so that both G0434 and G0431 only allow one bill to be submitted per patient encounter, regardless of how many drugs the UDT device tested for. The fact that labs were now prevented from submitting bills for each drug tested in a multi-drug test had the intended consequence of reducing laboratory reimbursements. This significant change had adverse financial implications for providers like Carolinas, whose laboratories processed numerous UDT screens.

CAROLINAS’ LABORATORY SYSTEM

A. Carolinas’ UDT Equipment Classification

28. Beckman Coulter, (“Beckman”), is a developer, manufacturer, and marketer of biomedical testing devices. One of Beckman’s devices, the UniCel DxC 800 Synchron Systems (“DxC 800”), is used by Carolinas to perform all of the UDT in the laboratories in the Primary Enterprise facilities, i.e. the hospitals that comprise the CMC system and Anson Hospital, CMC-Union, CMC-Pineville, Northeast, University, Kings Mountain and Stanly hospitals. The DxC 800 is a basic drug screening machine that tests a urine sample for six different drugs. Carolinas’

laboratories conducted its drug tests on the DxC 800. All drug tests performed on the DxC 800 cover the same number of drugs and are qualitative in nature - meaning they provide only a positive or negative result with respect to the drugs tested for, not a quantitative amount.

29. The FDA classified the Beckman DxC 800 as a moderate complexity system. Carolinas' laboratories are certified to perform moderate complexity UDT and do not have any equipment that is classified as high complexity for purposes of UDT.

B. Carolinas' Chargemaster Billing System

30. Carolinas uses a chargemaster billing system for its CMC, Mercy, Lincoln, Anson, Union, Pineville, Northeast, University, Kings Mountain, and Stanly hospitals. Chargemaster is a hospital-specific computer file that includes information about all hospital procedures, services, supplies, and drugs that are billed on the UB-92 form - the official CMS form used by hospitals when submitting bills to Medicare for reimbursement for health services provided to Medicare patients.

31. Carolinas chargemaster system includes an item description, which describes the particular supply, device, medication, service, procedure, or other item provided or performed. The chargemaster also includes the corresponding Current Procedural Terminology ("CPT") or Level II Healthcare Common Procedure Coding System ("HCPCS") code that identifies the specific service or procedure. The charge dollar amount is also part of chargemaster and represents the amount charged for the particular item.

32. Chargemaster maintenance is usually assigned to an individual in the finance or business office area of Carolinas, and the designated hospital is responsible for maintaining the chargemaster for all of Carolinas' Primary Enterprise facilities. The chargemaster designee is responsible for reviewing the chargemaster and for making any changes due to HCPCS or CPT code updates, new services being added, or charge increases or decreases. The billing codes in

chargemaster are supposed to be reviewed and updated regularly to ensure that the billing codes comply with CMS billing code instructions. Without an up to date and accurate chargemaster, Carolinas' facilities might not receive proper reimbursement for services rendered and would run the risk of overcharging government health insurers.

FACTS

33. On January 2, 2014, Relator reviewed CMC's chargemaster billing codes concerning the laboratory operations for which he was responsible. While reviewing these codes, Relator discovered that CMC was billing all UDT with the G0431 HCPCS code. Relator, who was the administrator for laboratory services, knew that CMC performed all of its drug screens on its Beckman DxC 800 system, and understood that the equipment could only perform moderately complex testing. Aware of the CMS reimbursement rules for UDT testing, he immediately realized that all of CMC's UDT claims submitted to Medicare and Medicaid should have been billed under HCPCS code G0434, which has a reimbursement rate \$80 lower than G0431.

34. In an effort to determine whether or not CMC had properly billed Medicare and Medicaid under the correct HCPCS code, Relator sent an email to CMC's Chemistry Medical Director. Relator asked CMC's Chemistry Medical Director which level of complexity corresponded to the Beckman DxC 800 system. CMC's Chemistry Medical Director told Relator that the testing complexity was moderately complex.

35. In Release SE1105, CMS instructed laboratories to contact the manufacturer of their equipment with any questions regarding their equipment's complexity classification. Following this advice, on the following day, January 3, 2014, CMC's Chemistry Medical Director emailed an employee of Beckman Coulter, the manufacturer of the DxC 800, to verify that the classification level of the DxC 800 was moderately complex. In that email, on which

Relator was copied, CMC's Chemistry Medical Director informed the Beckman Coulter employee that the information was needed in order to determine which billing code, G0431 or G0434, applied to tests conducted on the equipment. The Beckman Coulter employee confirmed that the Dx_C 800 system was "considered moderately complex."

36. Later that day, Relator emailed Carolinas' Laboratory Quality Director regarding his concern that Carolinas was improperly billing under the G0431 code instead of the G0434 code. Relator's email explained the differences between the two codes and he attached CMS Release SE1105 to the email. Carolinas' Laboratory Quality Director was responsible for administering all Carolinas labs in the Primary Enterprise.

37. On January 5, 2014, after receiving confirmation from the Beckman Coulter employee, CMC's Chemistry Medical Director emailed Carolinas' Laboratory Quality Director and Relator, informing them that the manufacturer had confirmed that CMC's UDT equipment was moderately complex. Notably, the January 5 email provided Carolinas' Laboratory Quality Director with all the information needed to confirm that Carolinas was billing Medicare improperly. Despite this knowledge, Carolinas did not change its UDT billing practices.

38. Carolinas' Laboratory Quality Director responded to CMC's Chemistry Medical Director's email on January 16, asking if CMC's Chemistry Medical Director was referring to the same concern Relator had expressed to Carolinas' Laboratory Quality Director in his January 3 email. Relator replied that it was in fact the same issue. Relator forwarded Carolinas' Laboratory Quality Director the email correspondence between CMC's Chemistry Medical Director and the Beckman Coulter employee. Carolinas' Laboratory Quality Director told Relator to make the change in chargemaster to reflect the proper CMS coding. Carolinas' Laboratory Quality Director also asked "Does this [coding problem] effect [sic] all sites?"

Relator informed Carolinas' Laboratory Quality Director that, to the best of his knowledge, the Anson, Mercy, Northeast, Lincoln, King's Mountain Cleveland Regional, Union, Carolinas Rehabilitation, Pineville, University, and the Reference laboratories all had the same coding problem.

39. After getting Carolinas' Laboratory Quality Director's approval to change the code, Relator contacted a Carolinas employee who was familiar with changing billing codes in chargemaster. Relator emailed that employee regarding the coding change to be made in chargemaster, writing "we need to convert existing Drug screen testing that occurs on our Beckman Coulter from a G0431 to a G0434." That employee told Relator that the chargemaster change could be completed by the following week.

40. On the evening of January 16, 2014, Carolinas' Laboratory Quality Director emailed Relator and asked him to find the price difference between G0431 and G0434 - "Can you find the pricing difference? We may need to refund". Carolinas' Laboratory Quality Director stated that the information was needed to determine if Carolinas was going to have to reimburse CMS for overbilling urine drug tests. On the morning of January 17, 2014, Relator emailed Carolinas' Laboratory Quality Director that the G0431 code's reimbursement rate was \$99.95 while the reimbursement rate for G0434 was \$19.99.

41. Only minutes after receiving Relator's email detailing the price difference in the two codes, Carolinas' Laboratory Quality Director emailed the employee familiar with changing billing codes in chargemaster, informing that employee to hold off on changing the chargemaster coding. In that email, Carolinas' Laboratory Quality Director wrote "[H]old off on any changed until I get advise [sic] from [Carolinas' Assistant Vice President of Laboratories]," the employee that oversees laboratory reimbursement and charge decisions. On January 29, Relator emailed

Carolinas' Laboratory Quality Director asking for an update on the UDT coding change. He did not receive a response.

42. On March 6, 2014, Relator emailed Carolinas' Laboratory Quality Director and Carolinas' Assistant Vice President of Laboratories. In his email, Relator stated that the urine drug tests "being performed on our Beckman instruments are Moderately complex, and that has been confirmed by Beckman Coulter. The CPT code for that is G0434. We have been reporting it under G0431. There is a \$80.00 difference in reimbursement." Again, Relator did not receive a response to his email.

43. By March 13, 2014, more than three months had passed since Relator had first brought the UDT upcoding problem to his superiors' attention and nothing had been done. Relator consulted the Carolinas HealthCare System Code of Business Conduct handbook to see how he should proceed. The Business Conduct handbook read, in relevant part, "Teammates are required to report known or suspected false claims violations immediately. Teammates can make reports to supervisors, their Facility Compliance Officer, the Corporate Compliance Department, or the Compliance HelpLine." Relator had already brought the upcoding issue to the attention of the Assistant Vice President and Carolinas' Laboratory Quality Director, and had made both aware that Carolinas' DxC 800 system was a moderate complexity test. Since neither employee had taken any action to resolve the upcoding problem, Relator decided to call the Compliance HelpLine.

44. The Compliance HelpLine is run by an independent company that documents the call. The HelpLine does not report compliance problems to the government and all records and other data gathered from the HelpLine are maintained by Carolinas Corporate Compliance Department. During the call, Relator provided a detailed explanation of the two billing codes,

and when each should be used. Relator explained that Carolinas had not implemented a required CMS change to these codes and had therefore been improperly billing these codes since January 1, 2011. Relator reiterated that he believed what was happening was wrong and that he was looking out for Carolinas' best interest. Relator also explained that he feared retaliation, since his supervisors were not acting on the information he provided.

45. On April 10, 2014, Relator called the HelpLine again to see if any action had been taken regarding the billing codes. He was told that no action had been taken and was asked for more information. Relator again emphasized that Carolinas was not billing correctly and told the HelpLine operator with whom he was speaking that Carolinas was not using the correct billing code for UDT tests and was therefore being overpaid by government health care programs. Relator got the strong impression that the individual who had reviewed the case did not understand the laboratory billing process.

46. On April 30, 2014, nearly four months after the Relator had informed CMC and Carolinas that the Carolinas system was routinely overcharging the government for urine testing, Carolinas' Assistant Vice President of Laboratories sent an email to CMC's Chemistry Medical Director and Carolinas' Laboratory Quality Director, in which the Assistant Vice President asked for clarification as to which billing code should be used for UDT. CMC's Chemistry Medical Director had already clarified which billing code should be used on several occasions. In response to the Assistant Vice President's request, CMC's Chemistry Medical Director reiterated that the DxC 800 UDT was a moderate complexity system. Relator and Carolinas' Laboratory Quality Director were copied on the email. No further action was taken.

47. On June 6, 2014, the Manager of Billing, Medicare/Medicare Advantage and Medical Necessity for CMC, emailed Carolinas' Manager of Billing & Chargemaster, and

Carolinas' Laboratory Quality Director, asking which billing code should be used for UDT performed on Carolinas' DxC 800 system. The Manager of Billing's email said that Carolinas was still using the G0431 billing code. On June 9, 2014, Carolinas' Manager of Billing & Chargemaster responded to the Manager of Billing's email, stating that "Medicare should be billed G0431." Carolinas' Manager of Billing & Chargemaster's email evidences a deliberate decision by Carolinas to upcode and to knowingly submit false claims to Medicare and the North Carolina Medicaid program.

48. On June 9, Carolinas' Laboratory Quality Director forwarded the correspondence between the Manager of Billing and the Manager of Billing & Chargemaster to Relator. Relator, responding to all recipients on the email chain, stated that Carolinas' in-house drug tests performed on the DxC 800 system were moderately complex tests and therefore had to be billed under the G0434 code. In his email, Relator wrote that, unless CMS made a determination to the contrary, Carolinas did not qualify for the G0431 code since that billing code was specifically reserved for high complexity testing methods. CMC's Chemistry Medical Director responded to the email chain, stating that Relator's analysis was "absolutely correct."

49. On June 17, Relator forwarded the Manager of Billing & Chargemaster several emails between himself, the employee familiar with changing billing codes in chargemaster, Carolinas' Laboratory Quality Director and the Assistant Vice President of Laboratories. The emails documented all of the steps Relator had taken to stop Carolinas' upcoding of UDT since he discovered the problem in January 2014. The emails also included Carolinas' Laboratory Quality Director's order to hold off on changing the charge codes for urine drug tests. Relator reiterated that Beckman Coulter, the manufacturer of the UDT equipment, filed its FDA approved complexity results under Moderately Complex. Relator was ignored.

50. Almost six months later, on December 12, 2014, Relator placed another call to the HelpLine to see if any progress had been made implementing a change to the billing codes. Relator was told that the HelpLine's opinion was that Carolinas' UDT equipment "met the definition of the G0431 code," and that no change to the billing codes was necessary. Relator was shocked and informed the HelpLine that they were wrong. There was simply no basis for finding that Carolinas' UDT laboratory equipment was capable of performing high complexity UDT or that the G0431 code can be used for any type of testing other than high complexity testing.

51. After speaking with the HelpLine, Relator emailed the Manager of Billing & Chargemaster, asking what the result was on the investigation into the UDT billing codes. Relator mentioned that he knew the UDT billing codes had not been changed and inquired if CMS had been contacted. Relator reminded the Manager of Billing & Chargemaster that Carolinas' DxC 800 was moderately complex. In a second email Relator sent to the Manager of Billing & Chargemaster later that day, he added, "[H]ere is how insurance companies are interpreting this...According to CMS, code G0431 now applies to high complexity test only ... Beckman Coulter filed for Moderately Complex with the FDA 510(k) for its drug kit testing, which is what we use. It is not high complexity." The Manager of Billing & Chargemaster responded to Relator "We have done the research. The coding is correct. I am including [the Assistant Vice President of Laboratories] for more input."

52. In fact, the Manager of Billing & Chargemaster was wrong. The coding was incorrect. The Manager of Billing & Chargemaster acknowledged as much ten days later. On December 22, the Manager of Billing & Chargemaster sent an email to Relator, Carolinas' Laboratory Quality Director, the employee familiar with changing billing codes in chargemaster,

CMC's Chemistry Medical Director, and the Assistant Vice President of Laboratories, in which the Manager of Billing & Chargemaster wrote that the CMS 2015 Manual clarified that the G0431 code was reserved solely for high complexity test methods and that the G0434 code should be used for moderately complex tests. The Manager of Billing & Chargemaster ended that email by stating that, effective January 1, 2015, Carolinas would be changing its coding from G0431 to G0434. In fact, the CMS 2015 Manual made no changes or clarifications to UDT reimbursement or the proper usage of Codes G0431 and G0435. The reimbursement rules on December 22, 2014 were the same as those in effect on January, 2014—the date the Relator discovered the improper billing—which were the same as had been in effect since early 2011.

53. Relator responded to the Manager of Billing & Chargemaster's email on the same day, writing, "Since the guidelines have been out since 2011, and nothing has changed with the interpretation (the high complexity wording has always been there), are we going back from 2011 to 2014 for adjustment?" The Manager of Billing & Chargemaster responded to Relator's email saying that the guidelines were further defined for 2015 and that no adjustment was necessary. Relator told the Manager of Billing & Chargemaster that that was incorrect, and that billing codes G0434 and G0431 had not been changed by CMS since 2011. On January 13, 2015, Relator forwarded to the Manager of Billing & Chargemaster a screen shot from the FDA filings showing that Beckman's DxC 800 was classified as a moderate complexity system.

54. On January 29, 2015, Carolinas updated the chargemaster for the primary enterprise facilities to charge in house drug screens performed with Carolinas' lab equipment under billing code G0434. This change updated the billing codes not only for CMC, but also for Anson, Mercy, Northeast, Lincoln, King's Mountain, Cleveland Regional, Union, Carolinas Rehab, Pineville, University, and Reference lab.

55. During the four year period during which Carolinas was upcoding UDT from Code G0434 to Code G0431, tens of thousands of upcoded UDT claims were presented to government health care programs for reimbursement.

CAROLINAS' CONDUCT VIOLATES THE FALSE CLAIMS ACT

56. Carolinas committed two separate frauds that violated the FCA. First, Carolinas violated the FCA by engaging in a scheme to fraudulently obtain falsely inflated payments from the government by impermissibly upcoding UDT billing codes. Second, Carolinas violated the reverse false claims provision of the FCA by knowingly avoiding its obligation to repay the government the millions of dollars in overpayments it illegally obtained through the upcoding of UDT.

A. Carolinas' Upcoding Scheme Violates the FCA

57. Carolinas intentional and improper upcoding of UDT resulted in Medicare and Medicaid making substantial overpayments for UDT performed by Carolinas' laboratories.

58. Upcoding began in 2011, when Carolina refused to make the coding changes required by Release SE1105. It is clear that Carolinas ignored the 2011 UDT billing code changes and submitted claims for all of its UDT testing under Code G0431, notwithstanding the fact that all of its testing was performed on equipment incapable of performing high complexity testing. Carolinas' failure to comply with unambiguous, reimbursement rules is inexcusable. One of the nation's largest and most sophisticated health care systems, Carolinas knew it was supposed to keep abreast of all CMS reimbursement changes, including those relating to UDT. Even if, unfathomably, Carolinas did not have actual knowledge of the issuance of SE1105, it certainly was aware of annual coding updates published by CMS. Carolinas' failure to educate itself with respect to CMS' 2011 UDT billing code update constitutes reckless disregard for the truth or falsity of the claims it submitted to CMS.

59. Multiple Carolinas employees knew about the upcoding practice and did nothing to stop it. Over the course of a year, Relator sent a series of emails to Carolinas' Laboratory Quality Director, the Assistant Vice President of Laboratories, the Manager of Billing & Chargemaster, and the Manager of Billing, continually informing all of them that Carolinas' UDT was performed on a moderate complexity system, which had to be billed under the modestly reimbursed G0434 code. Carolinas and CMC were repeatedly informed that they were incorrectly billing under the G0431 code.

60. From January 1, 2011, through January 29, 2015, each and every time Carolinas submitted a bill to a government health insurer using the G0431 code, Carolinas submitted a false claim, in violation of 31 U.S.C. § 3729(a)(1)(A).

B. Carolinas violated the Reverse False Claims Provision of the FCA

61. Pursuant to 31 U.S.C. § 3729(a)(1)(g) a person who "knowingly and improperly avoids or deceases an obligation to pay or transmit money or property to the Government" violates the False Claims Act. Section 3729(b)(3) defines an "obligation" to be "the retention of any overpayment." And pursuant to 42 U.S.C. § 1320a-7k(d)(3), any failure to repay an overpayment to the United States within sixty days after the overpayment is identified is also a violation of the False Claims Act.

62. Carolinas knew it had impermissibly retained payments made by the government in January 2014, when Relator told his superiors that Carolinas had been improperly billing the government for its UDT tests under Code G0431 instead of G0434 since January 2011. It was aware of its obligation to refund the difference between the two codes as early as January 16, 2014, when Carolinas' Laboratory Quality Director asked the Relator to find out what the difference in reimbursement was because Carolinas was going to have to repay it to the government. It was only when Carolinas' Laboratory Quality Director found out how much

money Carolinas had improperly taken from the United States that Carolinas' Laboratory Quality Director changed positions on properly reporting and repaying the difference. By January 17, 2014, Carolinas knew it had received overpayments and had to repay the difference.

63. Carolina certainly knew it had to reimburse the government when it finally updated the UDT billing codes on January 29, 2015. When Carolinas announced, on December 22, 2014, that it was changing its UDT billing codes to reflect the 2011 CMS changes, Relator specifically asked his superiors what they were going to do about the money Carolinas had received from improper upcoding:

Since the guidelines have been out since 2011, and nothing has changed with the interpretation (the High Complexity wording has always been there), are we going back from 2011 to 2014 for adjustment?

64. Only the Manager of Billing & Chargemaster responded to the Relator, informing him that Carolinas would not repay the overpayments because "(t)he guidelines are further define for 2015," a fact that Relator (and Carolinas) knew to be entirely inaccurate.

65. Carolinas has gone out of the way to punish the Relator for insisting that it repay the United States what is properly owed to it. At end of December 2014, Relator received his annual job performance review from an Assistant Vice President who works closely with the Assistant Vice President of Laboratories—the AVP who refused to change the Carolinas' chargemaster in 2014, but ultimately made the change for 2015. The reviewing Assistant Vice President gave the Relator a good evaluation, found that he met all expectations and gave the Relator a bonus and a raise.

66. However, in March 2015, shortly after the Relator advised Carolinas that it had to repay the overpayments it had received due to the upcoded UDT billing, the reviewing Assistant Vice President put Relator on a Performance Plan, the first step in terminating an employee. The

grounds for discipline were an alleged failure to carry out personnel changes that the reviewing Assistant Vice President had requested eleven months earlier. The grounds given were clearly pretextual. Had there been a legitimate failure to follow his supervisor's instructions months earlier, the reviewing Assistant Vice President would have flagged the issue at the Relator's annual review, would not have found that the Relator met all expectations and would not have awarded Relator a bonus or a raise. The Relator has clearly been disciplined because he sought to protect the government from fraudulent conduct.

67. Carolinas was aware that it had to reimburse the government for the overpayments it received as early as January 2014, and certainly by January 2015, but it simply did not want to sacrifice millions of dollars necessary to repay the obligation, especially given the financial difficulties it was experiencing. Carolinas' intentional failure to pay back government health care programs for fraudulently obtained overpayments are reverse false claims violations of the FCA.

COUNT I
VIOLATING FALSE CLAIMS ACT BY MAKING FALSE CLAIMS FOR PAYMENT
BY IMPROPERLY UPCODING URINE DRUG TESTS
31 U.S.C. § 3729(A)(1)(A)

68. Relator repeats and realleges each and every allegation in the paragraphs above as if fully set forth herein.

69. By reason of the acts described above, Carolinas knowingly presented or caused to be presented, false or fraudulent claims to the United States for payment or approval.

70. Carolinas set out on a deliberate campaign to fraudulently obtain falsely inflated payments from the Government by impermissibly upcoding UDT tests since January 1, 2011.

71. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*

72. By reason of the above described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT II

VIOLATING FALSE CLAIMS ACT BY KNOWINGLY FAILING TO FULFILL AN OBLIGATION TO PAY THE GOVERNMENT

31 U.S.C. § 3729(A)(1)(G)

73. Relator repeats and realleges each and every allegation in the paragraphs above as if fully set forth herein.

74. By reason of the acts described above, Carolinas knowingly failed to pay an obligation to the United States, within the meaning of 31 U.S.C. § 3729(a)(1)(G).

75. By reason of its violations of 31 U.S.C. § 3729(a)(1)(G), the United States was wrongfully denied a payment of a substantial amount and owing repayment of Medicare and Medicaid overpayments made to Carolinas pursuant to Carolinas' fraudulent UDT upcoding scheme.

COUNT III

VIOLATION OF 31 U.S.C. § 3730(h)

31 U.S.C. § 3730(h)(1)

76. Relator repeats and realleges each and every allegation in the paragraphs above as if fully set forth herein.

77. Relator was engaged in conduct protected by the anti-retaliation provision of the federal FCA, 31 U.S.C. § 3730(h)(1), because he is a Carolinas employee, and because of his efforts to stop Carolinas' violations of the FCA § 31 U.S.C. § 3729(a)(1)(G) and 31 U.S.C. § 3729(a)(1)(A).

78. Carolinas was aware that Relator was engaged in protected activity because the protected activity itself made Carolinas aware of it. Relator made efforts to stop Carolinas'

fraudulent practices by informing his peers and superiors on multiple occasions throughout 2014 that Carolinas was overbilling Medicare and Medicaid for UDT by improperly upcoding UDT bills, and that Carolinas was also impermissibly retaining payments received from government health care programs for the upcoded UDT.

79. Carolinas retaliated against Relator because of his protected conduct which demonstrated to Carolinas that Relator was certain of his concerns, was persistent in his efforts to stop Carolinas' violative practices, and was willing to go outside the company, evidenced by this call to the Helpline, to address them.

80. Carolinas' retaliatory conduct, prohibited by 31 U.S.C. § 3729(h)(1), included placing Relator on a Performance Plan - a first step towards termination. Relator fears further retaliatory conduct.

COUNT IV
VIOLATING NORTH CAROLINA FALSE CLAIMS ACT
N.C.G.S. §1-605 et seq.

81. Relator repeats and realleges the allegations set forth in paragraphs 1 through 80 as if fully set forth herein.

82. By virtue of the acts described above, Carolinas knowingly presented or caused to be presented to an officer or employee of a North Carolina agency a false claim for payment or approval, in violation of N.C.G.S. § 1-607(a)(1).

83. By virtue of the acts described above, Carolinas had possession, custody, or control of property or money used or to be used by the State and knowingly delivered less than all of that money or property, in violation of N.C.G.S. § 1-607(a)(4).

84. North Carolina, unaware of the falsity of the records, statements, and claims made, used, presented or caused to be made, used or presented by Carolinas, paid claims from

January 1, 2011 through January 29, 2015 that would not be paid but for the acts and/or conduct of Carolinas as alleged herein.

85. By reason of Carolinas' acts, the State of North Carolina has been damaged in a substantial amount to be determined at trial.

86. Pursuant to N.C.G.S. § 1-607(a), the State of North Carolina is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every made, used or presented by Carolinas.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States of America, requests that this Court:

Enter judgment holding Carolinas liable for a civil penalty of \$11,000 for each violation of the False Claims Act committed by the company;

Enter judgment holding Carolinas liable for three times the amount of damages sustained by the United States because of its acts;

Award Relator a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730;

Award Relator his reasonable attorneys' fees and the cost of bringing this action;

Reinstate Relator with the same seniority status that he would have had but for the wrongful retaliation;

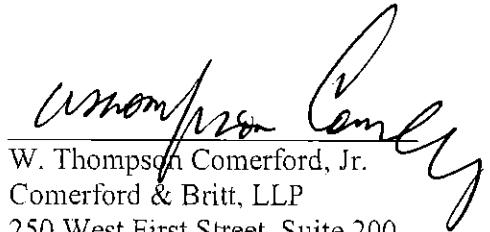
Award Relator compensation for all damages he has sustained as a result of Carolinas' retaliation; and

Enter such other relief which the Court finds just and equitable.

Respectfully submitted
MARK McGUIRE, on behalf of the
UNITED STATES OF AMERICA and the
STATE OF NORTH CAROLINA

Date: June 27, 2017

By their attorneys


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